

May 15, 2003

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-III-03-024

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region III staff on this date.

Facility

University of Wisconsin-Madison
Madison, Wisconsin
License No.: 48-09843-18
Docket No.: 030-03465

Licensee Emergency Classification

☐ Notification of Unusual Event
☐ Alert
☐ Site Area Emergency
☐ General Emergency
☒ Not Applicable

SUBJECT: Reported Medical Event Involving Yttrium-90 Microspheres (Underdose)

On May 14, 2003, the licensee reported that a medical event had occurred involving a yttrium-90 (Y-90) liver treatment that resulted in an administered dose that was only 3.5 percent of the prescribed dose. An individual who was prescribed a dose of [REDACTED] of Y-90 only received [REDACTED] due to a procedural error during a May 13, 2003, treatment session. The Y-90 was in the form of insoluble resin microspheres, and was being injected into the patient's liver in a saline solution. The licensee speculated that the staff pierced the seal on the vial containing the microspheres several times, creating a leak that reduced the air pressure below that required to force the microspheres into the treatment device.

The licensee is planning to conduct a second treatment of the patient. The licensee is also implementing additional controls to prevent recurrence of this type of event. The vendor of the device (Sirtex Medical Limited) will be onsite monitoring the second patient treatment and to provide additional training to the licensee staff. NRC Region III plans to conduct a special inspection to review the circumstances surrounding the reported medical event.

The NRC's Office of Nuclear Materials Safety and Safeguards and the State of Wisconsin have been notified. The NRC's Operations Center was notified of the medical event at 12:35 p.m. EDT on May 14, 2003. The information in this preliminary notification has been reviewed with licensee management. This information is current as of 9:00 a.m. CDT on May 15, 2003.

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